

Prenylflavanoids as a biomarker of beer consumption

Submission date 24/04/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/05/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/05/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Prenylflavanoids (a group of plant hormones) are mainly found in hops, and therefore, in beer. Thus, the intake of beer might be assessed through its quantity present in the urine. The aim of this study is to assess the usefulness of urinary prenylflavanoids as a biomarker of beer consumption.

Who can participate?

Healthy adults, in the age range 18-35 years, non-smokers, without previous history of heart, liver or kidney disease, disorders with body balance, any other long-lasting diseases, high blood pressure or Dyslipidemia (abnormal cholesterol/fat level in the blood), alcoholism or other toxic abuse.

What does the study involve?

The volunteers were given different doses of beer at dinner in a random order. Male volunteers consumed 330, 660 and 990 ml of beer, and female volunteers consumed 330, 495 and 660 ml of beer. Before each dose, volunteers followed a 4-day wash-out period in which they were requested to avoid consuming any type of hop-based products and beer. Urine sample was collected before each dose.

What are the possible benefits and risks of participating?

There are no risks as long as the exclusion criteria are followed. The study was conducted according to the Declaration of Helsinki of the World Medical Association. The study was explained to subjects through verbal and written instructions, and written informed consent was obtained before participation.

Where is the study run from?

This study involved the Department of Nutrition and Food Science of the University of Barcelona (Barcelona, Spain) and the Department of Internal Medicine, Hospital Clinic, Institut d'Investigació Biomèdica August Pi i Sunyer (IDIBAPS), University of Barcelona (Barcelona, Spain).

When is the study starting and how long is it expected to run for?

This study was conducted between March 2011 and October 2011.

Who is funding the study?

This study was supported by the European Foundation for Alcohol Research (ERAB) (Belgium).

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Urinary isoxanthohumol excretion as a biomarker of beer consumption

Study objectives

Hops and beer are a unique source of xanthohumol, isoxanthohumol and 8-prenylrningenin. Therefore, prenylflavanoids, such as isoxanthohumol and their metabolites may be a potent biomarker of beer consumption, thus the intake of beer can be assessed by quantifying isoxanthohumol in urine.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of University of Barcelona (Institutional Review Board IRB00003099), 04/07/2011

Study design

Dose-response randomised cross-over clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Beer consumption

Interventions

Male volunteers:

Intervention 1: Administration of 330 mL beer (14.5 g ethanol)

Intervention 2: Administration of 660 mL beer (29 g ethanol)

Intervention 3: Administration of 990 mL beer (43.5 g ethanol)

Female volunteers:

Intervention 1: Administration of 330 mL beer (14.5 g ethanol)

Intervention 2: Administration of 495 mL beer (21.7 g ethanol)

Intervention 3: Administration of 660 mL beer (29 g ethanol)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Concentrations of urinary prenylflavanoids will be determined by liquid chromatography coupled to tandem mass spectrometry (LCMS/MS). These determinations will be carried out in first morning urine samples collected the day before the first intervention and in the subsequent mornings following each intervention. Creatinine adjustment will be used to normalize analyte concentrations in these urine samples.

Secondary outcome measures

No secondary outcome measures

Overall study start date

31/03/2011

Completion date

28/10/2011

Eligibility

Key inclusion criteria

Young healthy volunteers of age 28 ± 3 years, body mass index 22.69 ± 2.69 kg/m²

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

41 (20 men and 21 women)

Key exclusion criteria

1. Previous history of cardiovascular disease (ischemic heart disease criteria - angina, recent or old myocardial infarction, cerebral vascular accident or peripheral vascular disease)
2. Homeostatic disorders
3. Any several chronic diseases
4. Hypertension or dyslipidemia
5. Smoking subjects
6. Alcoholism
7. Other toxic abuse

Date of first enrolment

31/03/2011

Date of final enrolment

28/10/2011

Locations

Countries of recruitment

Spain

Study participating centre

Av. Joan XXII s/n
Barcelona
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Sponsor information

Organisation

Center for Biomedical Research in Pathophysiology of Obesity & Nutrition (Ciber Fisiopatología de la Obesidad Nutrición)(Spain)

Sponsor details

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Sponsor type

Research organisation

ROR

<https://ror.org/02s65tk16>

Funder(s)

Funder type

Research organisation

Funder Name

Center for Biomedical Research in Pathophysiology of Obesity and Nutrition (CIBERObn) (Spain)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No